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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,466	06/27/2003	Laszlo Vertesy	DEA V2002/0046US NP	9365

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EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,466

Applicant(s)

VERTESY ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-15 is/are allowed.
- 6) ☒ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/12/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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The Status of Claims:

Claims 1-23 are pending.

Claims 16-23 have been rejected.

Claims 1-15 are allowable.

DETAILED ACTION

Priority

Claims 1-23 are under consideration in the application.

I It is noted that this application claims a benefit of 60/423,473 (11/04/02); the examiner has acknowledged that foreign priority documents, Germany 10229713.4 (7/2/02) has been filed.

Drawings

II None.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 20-21, the phrase “ A method for the treatment and/or prophylaxis of an infectious bacterial disease” is recited. However, the specification does not describe how to prevent an infectious bacterial disease and also, there are no showings of any evidence for “preventing and treating the infectious bacterial disease ”at the same time. Furthermore, the contemporary knowledge of the art does not teach “ how to prevent “ for all the infectious bacterial diseases. If we could prevent all the possible permutations and combinations of the above, nobody would be sick. In addition, more than routine experimentation is involved. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al. , 190 USPQ 152 (CCPA 1990). Therefore, the specification has failed to support enablement for the method for treating and/or preventing dementia. Therefore, an appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 16, the phrases "where appropriate" and "another compound of formula (I)" are recited. These expressions are vague and indefinite because the specification does not explain when and where it is appropriate to use a suitable reagent to convert the serpentemycin A, B, C or D into another compound of formula (I). Also, there are no concrete examples for another compound of formula (I) with respect to the converted serpentemycin A, B, C or D compounds. Therefore, an appropriate correction is required.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: specifying the reaction conditions, such as, temperature, pressure, catalyst, and etc is absent during the processing step of converting said serpentemycin A, B, C or D into another compound of formula (I). This step is essential because the outcome of the desired final products is dependent on the reaction conditions in the process.

In claim 18, the phrase "where appropriate" is recited. These expressions are vague and indefinite because the specification does not explain when and where it is appropriate to convert the compound of formula (I) into a pharmacologically tolerated salt. Therefore, an appropriate correction is required.

In claims 20-21, the phrase "A method for the treatment and/or prophylaxis of an infectious bacterial disease" is recited. The expression of "the treatment and/or prophylaxis of an infectious bacterial disease" is vague and infinite because of its Reach-Through Claim. The claim does read on the future treatment of any infectious bacterial diseases which have not discovered yet. In order to overcome this rejection, the examiner recommends to add the specific infectious bacterial diseases in the instant invention. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 23 is rejected under 35 U.S.C. 102(a) as being anticipated clearly by Deutsche Sammlung (3/18/2002).

Deutsche Sammlung discloses the isolation of Actinomycetales sp. DSM 14865 shown in the specification (page from 11, line 31 to page 12, line 2). This is identical with the claim.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Taylor Victor Oh
9/14/04

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